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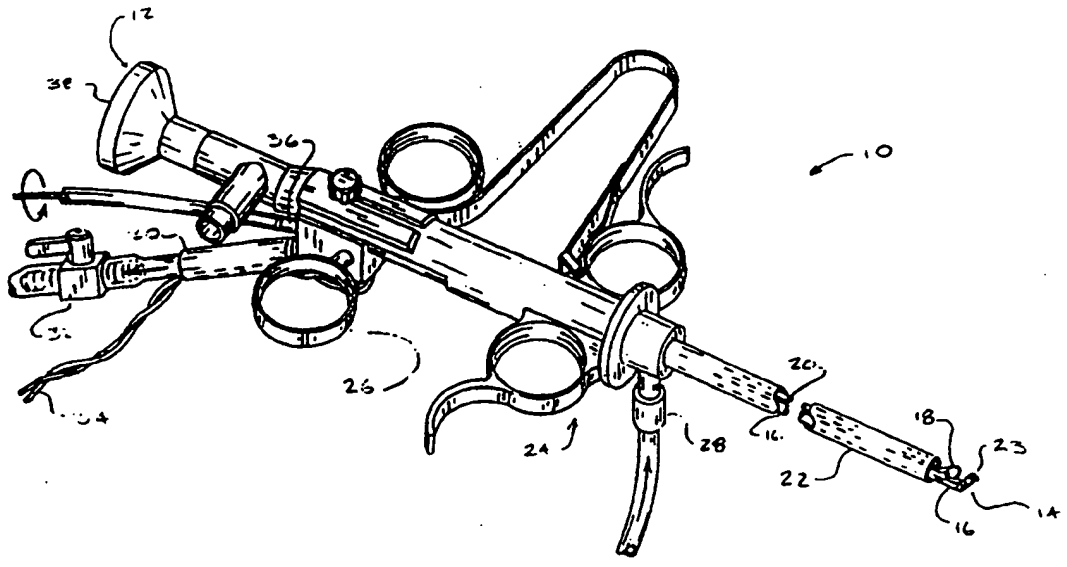
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(54) Title: TISSUE RESECTION DEVICE HAVING A REMOVABLE ABLATION/COAGULATION CLIP



(57) Abstract

The present invention provides a tissue resection device comprising a shaft (22) having an aperture, a cutting member (18) disposed adjacent to the aperture, and a chopping mechanism disposed within the lumen of the shaft. An electrically conductive surface (23) is disposed near the cutting member (18) to apply coagulative or ablative energy to a surface of remaining tissue. Preferably, the cutting member (18) comprises a transverse electrosurgical cutting wire, and the conductive surface (23) comprises a roller aligned with the wire so that as the wire severs a strip of tissue proximally, the strip is aspirated through the aperture while the roller cauterizes any open blood vessels.

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TISSUE RESECTION DEVICE HAVING A REMOVABLE ABLATION/COAGULATION CLIP

BACKGROUND OF THE INVENTION

This invention relates to a method and device for tissue resection, especially for surgical treatment of the uterus or prostate.

Electrocautery has been in use for many years as a general surgical tool, such as for transcervical fibroid removal. The uterus is first flooded (typically with a nonconductive fluid, such as sorbitol-mannitol fluid or the like) under sufficient pressure to separate the walls of the uterus and render the surgical site suitable for optical fiber observation. This procedure is generally described as uterine cavity distension. During this flooding, an electrocautery surgical tool is inserted into the uterus through the cervix. Electrical current at high voltage settings (typically an alternating current about 750 KHz and 2000-9000 volts) is transmitted from a cutting surface of the surgical instrument to the surgical site. The cutting surface usually consists of a wire or solid shape. The transmission of current to the uterus is monopolar, and the circuit is completed by a conductive path to the power unit through a conductive pad applied to the patient's skin.

The electrical current is concentrated at the cutting surface. Heat generated from the resistance of tissue to the flow of electrical current is high enough to vaporize

cells near the cutting surface. Thus, a cut is made with very little physical resistance to the cutting motion. Heat from the cut cauterizes small blood vessels so that visibility and control remain good.

During uterine cavity distension, a similar electrical resistance heating may be used at lower power settings to cauterize bleeding tissue and to kill selected areas of the tissue through ablation. Such cautery electrodes can be larger in area so as to treat broader surfaces. Cautery is used in gynecology to ablate the endometrial lining of the uterus. This procedure is often performed using a conductive roller which heats a wide swath of tissue along the inner surface of the uterus.

Electrocautery tools are compact and require a minimum of area in which to work. Since the tool only cuts when the power is turned on, it can be safely maneuvered into small areas. Electrocautery has found broad general application in the treatment of enlarged prostate glands and in the removal of uterine fibroids.

A secondary effect of the removal of tissue, particularly in the area of fibroid removal, is that separated tissue fragments typically remain in the working area and must be periodically flushed or suctioned away to preserve the required visibility necessary for surgery. The clean, well-controlled action of electrocautery is now slowed by this need to remove fragments which obstruct visibility. Therefore, the requirement for intermittent clearing of the surgical site prolongs fibroid removal and other electrosurgical procedures.

U.S. Patent Application Serial No. 08/136,426, the full disclosure of which is incorporated herein by reference, describes an exemplary resection method and device including a rotating cutting head which chops resected tissue into fragments, thereby facilitating the evacuation of resected tissue through the electrosurgical probe. U.S. Patent Application Serial No. 08/322,680, which is also incorporated herein by reference, provides resection methods and devices including both a rotating chopping mechanism and an electrosurgical cutting wire. The electrosurgical cutting

wire is particularly well-suited for removal of strips of tissue from the uterus, prostate, or other internal body cavities. The rotating chopping mechanism severs the strips of removed tissue into tissue fragments, allowing the electrosurgical cutting wire and rotating chopping mechanisms to be independently optimized for these two distinct cutting operations.

Parent U.S. Patent Application Serial No. 08/542,289, the disclosure of which is also incorporated herein by reference, describes the use of a probe having an electrosurgical cutting wire and a tissue chopping mechanism in combination with a distally oriented electrically conductive surface. This conductive surface facilitates the treatment of proximally oriented tissues of the body cavity through the application of ablative energy, and also allows cauterization of blood vessels left bleeding by the cutting wire. Preferably, resection and ablation/ coagulation are directed using a distally oriented scope attached to the probe.

Although the resection methods and devices described above are highly effective, electrosurgical resection methods could benefit from still further improvements. In a first aspect, as both the electrosurgical cutting wire and the ablation/coagulation surface extend radially from the probe, they tend to interfere with each other to some extent. Specifically, the ablation/coagulation surface can limit the depth of tissue cut by the wire, while the wire may have to distend resected tissue of the body cavity to bring the ablation/coagulation surface into contact with a bleeding blood vessel. In a second aspect, separate strokes to first pass the electrosurgical cutting wire through tissue, and to later individually cauterize any blood vessels which remain open with the ablation/coagulation surface, can result in a time consuming procedure when a large number of blood vessels are involved.

It would therefore be beneficial to provide improved resection methods and devices to overcome the limitations described above. It would be particularly advantageous if

such improved resection devices overcame the interference between the ablation/coagulation surface and the cutting wire. It would be especially advantageous if such improvements enabled a single probe to simultaneously electrosurgically remove tissue and coagulate open blood vessels, decreasing the time required for the complete resection procedure.

SUMMARY OF THE INVENTION

In a first aspect, the present invention provides a tissue resection device comprising a shaft having a proximal end and a distal end, with an electrosurgical cutting member disposed near the distal end of the shaft to sever tissue as the shaft is translated. An electrically conductive surface, typically comprising a roller, is disposed near the cutting member to apply coagulative or ablative energy to a severed surface of remaining tissue. Preferably, the cutting member comprises a transverse cutting wire, the wire and the roller typically protruding radially from the shaft and axially aligned. This arrangement facilitates rolling of the conductive cauterizing surface across any open blood vessels directly after the tissue strip is removed, separating the cutting and cauterizing functions into two independently optimized structures and power systems, and also minimizing the drag encountered during each stroke of the probe. Ideally, the conductive surface is removably mounted to the shaft, thereby avoiding any interference to the cutting process when coagulation and/or ablation is not required.

In another aspect, the present invention provides a tissue resection device comprising a shaft having an aperture adjacent to a distal end and a fluid and tissue aspiration lumen extending from the aperture to a proximal end of the shaft. A cutting member is disposed adjacent to the aperture to sever tissue as the shaft is translated, and a chopping mechanism disposed within the lumen of the shaft reduces the size of tissues passing through the lumen. An electrically conductive surface is disposed near the cutting member to apply coagulative or ablative energy to a surface of remaining tissue. Preferably, the cutting member comprises a transverse

electrosurgical cutting wire, at least a portion of the aperture ideally being disposed between the wire and the conductive surface. In a particularly advantageous embodiment, the conductive surface comprises a transverse roller aligned with the wire so that as the wire severs a strip of tissue proximally, the strip is directed into the aperture, after which the roller immediately cauterizes any open blood vessels.

Ideally, interference between the cutting member and the conductive surfaces is avoided by removing the conductive surface from the probe when it is not needed. Such a structure also promotes the use of specialized conductive surfaces which are removably mountable onto the probe, such as rollers, balls, distal ablation surfaces, and the like. Generally, the conductive surface extends resiliently beyond the wire so that the conductive surface may be used alone or deflected out of the way of the cutting member. Such a resilient mounting may also help maintain contact between the conductive surface and the remaining tissue surface during variations in cutting depth, and also at the beginning and end of each cut. In a final alternative, a retractable conductive surface will provide a flexible probe which need not be removed from the patient body to vary the cutting wire/conductive surface interaction.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a resection probe according to the principles of the present invention, showing a proximal handle and several of the probe system connections.

Fig. 2 illustrates a resection probe system, including the probe of Fig. 1.

Fig. 3 illustrates a method of use of the probe of Fig. 1 for transcervical fibroid removal from the uterus.

Figs. 4-4B illustrate alternative removable ablation/coagulation roller clips which removably attach near the distal end of the shaft, for use with the probe of Fig. 1.

Fig. 5 illustrates an alternative removable ablation/coagulation roller clip for use with the probe of Fig. 4.

Fig. 6 illustrates a retractable ablation/coagulation roller for use with the probe of Fig. 1.

Fig. 7 illustrates a resiliently mounted ablation/coagulation roller for use with the probe of Fig. 1.

Fig. 8 illustrates a removable coagulation/ablation roller which removably mounts to the cutting wire, for use with the probe of Fig. 1.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Referring now to Fig. 1, resection probe 10 generally has a proximal end 12 and a distal end 14. A probe shaft 16 supports a cutting member 18 near its distal end. An imaging scope 20 is distally oriented toward cutting member 18, and runs proximally within sheath 22. Scope 20 typically comprises a rod-lens imaging scope, alternatively being a fiber-optic scope. A coagulation/ablation roller 23 is disposed near the distal end 14 of shaft 16.

A probe handle housing 24 includes an actuation handle 26 for axially translating the shaft and cutting member relative to the sheath. An irrigation fluid port 28 and aspiration port 30 provide a continuous flow path for a clear, non-conductive fluid such as sorbitol-mannitol, mannitol, glycine, or the like. Aspiration flow is controlled by an aspiration valve 32, so that the distension pressure may be maintained independently from flow. Electrosurgical connector wires 34 and a flex drive input 36 provide external electrical and mechanical power, minimizing the weight of housing 24. An optical image eyepiece 38 is removably attached to housing 24 to optically direct the resection procedure. Optionally, an ultrasound transceiver may be mounted on the distal end of the probe, as is more fully explained in U.S. Patent Application Serial No. 08/322,680. Such a distal ultrasound transducer may optionally comprise a one- or two-dimensional phased array to allow scanning of the resection tissue independent of any mechanical movement of the transducer probe.

Referring now to Fig. 2, a resection system 40 utilizes the input and output connectors on the housing of probe 10, together with standard stand-alone surgical system components, to minimize cost, weight, and fatigue when using probe 10 in a resection procedure. An irrigation supply 41 is connected to irrigation port 28 to provide a continuous flow of irrigation fluid during resection. Preferably, irrigation supply 41 comprises a standard irrigation supply bag suspended above the surgical site to provide a constant pressure gravity feed, allowing distension pressure to be varied simply by changing the height of the irrigation supply. Alternatively, a valve or controlled flow pump may be used to supply irrigation fluid.

In the exemplary embodiment, aspiration, mechanical rotation, and electrosurgical potential are coupled to the shaft through a disposable cartridge 25 on shaft housing 24, the disposable cartridge reciprocating with the shaft as shown. This disposable cartridge structure facilitates replacement of the cutting wire/shaft assembly (including the inner and outer tubes of the chopping mechanism) which would otherwise limit probe life. Fluid which leaves aspiration port 30 is directed through a filter canister 42 and then to an aspiration sump 44. Filter 42 removes the solid tissue fragments from the aspiration fluid for analysis. Sump 44 is preferably connected to a standard vacuum supply line to promote the withdrawal of aspiration fluid through the probe. Aspiration vacuum control is conveniently provided by aspiration valve 32 (see Fig. 1).

Mechanical power is supplied to flex drive input 36 by drive motor 48. Drive motor 48 preferably rotates at least in the range between 500 and 1500 rpm, and typically allows for rotation in either direction, or oscillating rotation back and forth. The chopping mechanism generally shears tissue mechanically, without requiring electrosurgical potential.

Controlled electrosurgical power is supplied through electrosurgical wires 34 to the cutting member by power unit 46. A switch (not shown) allows application of electrosurgical power to be directed to roller 23. The

electrical potential may be conducted distally through shaft 16, or separate wires coupled to the roller may alternatively be provided. Preferably, roller 23 and cutting member 18 may be energized simultaneously, and ideally, using independently variable power. Optionally, an additional separate power supply 46 energizes the roller. The irrigation and aspiration flow paths, together with the optical viewing scope, are more fully described in copending U.S. Patent Application Serial No. 08/542,289, the full disclosure of which is herein incorporated by reference.

Referring to Fig. 3, an exemplary method for using resection probe 10 typically comprises transcervically introducing sheath 22 into the uterus U. Such insertion is facilitated by use of an obturator. Sheath 22 is preferably rigid, ideally comprising a composite insulating material such as fiberglass or the like. Manipulation of the probe is facilitated by limiting the sheath to a maximum of about 27 Fr (about 9 mm in diameter). Once the sheath is properly positioned, the obturator is removed and the shaft 16, cutting member 18, and the scope 20 are inserted through the shaft and proximal housing 24 is attached to sheath coupling 50.

The probe is manipulated from the proximal housing 24 using articulation handle 26. The surgeon inserts the fingers of one hand through finger handle 70, and inserts the thumb of the same hand through thumb ring 72. Preferably, the fingers are held stationary while the thumb ring extends the shaft and cutting member distally from the sheath. Thumb ring 72 is biased toward the proximal direction, so that removal of strips of tissue typically takes place under the assistance of biasing spring 73.

Removal of fibroid tissue from the uterus U begins with the cutting member 18 extended distally from the sheath 22 and energized with RF power, as described above. As illustrated in Fig. 3, the shaft is generally aligned with the tissue to be removed so that proximally actuating thumb ring 72 draws cutting member 18 through the fibroid tissue. The procedure is directed using scope 20, preferably while the scope and sheath are held substantially motionless using

finger handle 70. Performing each cut towards the viewing optics helps to avoid inadvertently perforating uterus U, the cutting member defining a maximum depth of the cut.

As illustrated, resiliently mounting roller 23 to shaft 16 allows the roller to protrude radially beyond the cutting wire, but also allows the roller to be displaced by pressing the roller out of the way during cutting. In some embodiments of the resection method of the present invention, no energy is supplied to the roller during this tissue removal, hence, the roller is optionally removed or retracted during the cutting stroke, as described hereinbelow.

In an alternative embodiment of the method of the present invention, the surgeon may manipulate the thumb ring relative to the finger handle to bring the cutting member 18 to a preferred viewing distance from scope 20, and then translate the shaft and housing assemblies together proximally. This provides a longer cutting stroke for cutting member 18, and decreases the time required for the resection procedure. Regardless, proximally oriented tissues 76 cannot easily be cut by such a proximal translation, and a proximal cutting direction also limits the ability of the probe to remove axially oriented tissue 78 near the far end of the cavity.

The difficult to reach areas, and any bleeders left open by the cutting wire, are treated by heating the tissue with roller 23 (or with some other ablation electrode shape). Roller 23 applies coagulation electrocautery current to a larger area of tissue than the cutting wire, creating heat which stops bleeding and/or kills endometrium. Roller 23 may be separately energized and rolled over the fundus (top of the uterus), the entrance to the fallopian tube, or other proximally oriented fibroid tissue 76 and adjacent axially oriented tissue 78, ablating these tissues without cutting or puncturing the wall of the uterus. The roller may also be independently energized after one or more strips of tissue have been severed and aspirated to cauterize any blood vessels which are left bleeding by the cutting wire. During such ablation or coagulation, no energy need be supplied to the

cutting member, with the coagulation surface preferably extending radially beyond the cutting wire and into a clear field of view of the scope.

In a still further embodiment of the resection method according to the present invention, the roller and the cutting member may be simultaneously energized during the cutting stroke. The roller is aligned with the cutting member, and will coagulate any open blood vessels very soon after they are severed, minimizing both the time required for the procedure and the blood loss, and thus also improving image clarity. By aligning the aperture axially between the cutting wire and the roller, severing of tissue, aspiration of the severed tissue, and coagulative heating may be applied simultaneously during each proximal stroke of the probe.

Referring now to Fig. 4, the orientation and flow of aspiration flow path 80 over the imaging fiber-optics 20 is illustrated. In the exemplary embodiment, the proximal ends of cutting member 18 are disposed within and electrically insulated from support tubes which are soldered to shaft 16, the tubes and shaft being insulated with shrink-wrap tubing 82. The interaction of shaving port 56 on chopping tube 58 with aperture 54 of shaft 16 is also clearly seen.

In the embodiment of Fig. 4, roller 23 is removably mounted on shaft 16 with a mounting clip 82. Resilient arms 84 allow radial movement of the roller axis (see Fig. 3), while collar 86 removably holds the roller in place, optionally coupling the roller to shaft 16 to provide electrical potential. Such a clip-on ablation roller avoids the need for a second specialized disposable cutter for treatment of proximally oriented surfaces. Several inexpensive rollers of different shapes could be used for more flexible and complete treatment, such as ball 86 shown in Fig. 5.

Referring now to Figs. 4A and B, an alternative mounting clip 83 comprises a closed end tube 85 having an aperture which is at least as large as the aspiration aperture on shaft 16. Closed end tube 85 slides over the distal end of shaft 16 with a friction fit, the closed end ensuring proper

axial alignment with the shaft. Arms 87 supporting roller 23 are affixed to the outer surface of the closed end tube. A preferred mounting clip 91 is formed from tubing which slides over the end of the shaft with a friction fit, a stop tab 93 ensuring axial alignment. Preferred clip 91 also has an upper tab folded over roughly 180° to form a rotational alignment key 95. This key mates with the shape of material removed from the end of the shaft to ensure rotational alignment of preferred clip 91 with the shaft of the probe. Resilient angled arms 97 allow deflection of the roller axis. Here, an optional smooth roller 99 is shown with no grooves.

The ability to snap mounting clip 82 on and off the tip of the cutting member/shaft assembly allows removal of the bulk of the endometrium/myometrium prior to attachment of, and thus without interference from, the coagulation surface. As required, the cutting member/shaft assembly is removed from the uterus through the sheath, and the desired ablation ball or roller clipped onto the distal end. The probe is then reinserted through the sheath, and the attached roller may be used to stop bleeders, to treat the top of the uterus, and to touch up areas which have been missed by the wire. The surgeon can thus alternate between the wire alone and various rollers as appropriate for the individual procedure.

Fig. 6 illustrates a distal end of a retractable roller probe 90 having a retractable roller 92 which is actuated from the proximal end of the probe using pull wire 94. The roller is again supported on resilient arms which allow the roller's axis of rotation to be displaced toward the axis of the shaft, as shown.

Referring now to Figs. 7 and 8, a resilient roller probe 100 supports resiliently mounted roller 102 on separate electrical lead wires 104. These resilient wires extend proximally along the shaft within the shrink-wrap tubing insulation, optionally also being insulated from shaft 16 within tubes fixed to the shaft, as described above regarding cutting member wires 82. In a still further alternative, detachable roller 116 might be mounted on cutting member 18, also by removing the shaft and cutting member through sheath

22. This allows the electrosurgical wires which supply power to the cutting member to also power the ablation or coagulation processes using the electrically conductive surface.

Although the foregoing invention has been described in detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modification may be practiced in the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A tissue resection device comprising:

a shaft having a proximal end and a distal end;

an electrosurgical cutting member disposed near the distal end of the shaft to sever tissue as the shaft is translated; and

an electrically conductive surface disposed near the cutting member to apply coagulative or ablative energy to a severed surface of remaining tissue.

2. A tissue resection device as claimed in claim 1, wherein the cutting member comprises a transverse axial wire to sever tissue as the shaft is reciprocated.

3. A tissue resection device as claimed in claim 2, wherein the conductive surface comprises a transverse roller, and wherein the roller and the wire are axially aligned and protrude radially from the shaft.

4. A tissue resection device as claimed in claim 3, wherein the roller is removably mounted to the shaft.

5. A tissue resection device as claimed in claim 3, wherein the roller is resiliently mounted to the shaft.

6. A tissue resection device comprising:

a shaft having a proximal end, a distal end, an aperture adjacent the distal end, and a fluid and tissue aspiration lumen extending from the aperture to the proximal end;

a cutting member disposed adjacent to the aperture to sever tissue as the shaft is translated;

a chopping mechanism disposed within the lumen of the shaft to reduce the size of tissue passing through the lumen; and

an electrically conductive surface disposed near the cutting member to apply coagulative or ablative energy to a surface of remaining tissue.

7. A tissue resection device as claimed in claim 6, wherein the cutting member comprises a transverse cutting wire and wherein the aperture extends axially of the wire.

8. A tissue resection device as claimed in claim 7, wherein the conductive surface comprises a transverse roller axially aligned with the wire.

9. A tissue resection device as claimed in claim 8, wherein at least a portion of the aperture is between the wire and the roller along the axis of the shaft.

10. A tissue resection device as claimed in claim 7, further comprising a proximal housing reciprocatably supporting the shaft, the proximal housing having an infusion lumen along the shaft with a fluid outlet near the distal end and an imaging mechanism oriented distally toward the cutting member and the conductive surface from the fluid outlet, wherein the roller extends distally of the shaft to ablate proximally oriented tissues.

11. A tissue resection device as claimed in claim 6, wherein the cutting member is transversely oriented and the cutting member and the conductive surface protrude radially from the same side of the shaft.

12. A tissue resection device as claimed in claim 11, wherein the conductive surface is removably mounted to the shaft.

13. A tissue resection device as claimed in claim 12, further comprising an alternative conductive surface which is removably mountable to the shaft, the alternative

conductive surface having a different shape than the conductive surface.

14. A tissue resection device as claimed in claim 11, wherein the conductive surface is resiliently mounted to the shaft.

15. A tissue resection device as claimed in claim 11, wherein the conductive surface is retractable.

16. A method for resecting internal tissue from a surgical site, the method comprising:

severing strips of tissue from the surgical site by translating a cutting member of a probe;

aspirating fluid from the surgical site into an aperture on a shaft of the probe so that the strips of tissue enter the aperture;

chopping the strips of tissue into tissue fragments as they enter the aperture and evacuating the tissue fragments through the shaft of the probe; and

cauterizing a severed surface of remaining internal tissue with an electrically conductive roller of the probe.

17. A method as claimed in claim 16, wherein the severing step and the cauterizing step are performed simultaneously.

18. A method as claimed in claim 16, further comprising introducing the probe into the surgical site within a sheath, removing probe from the sheath, and detachably mounting the roller onto the probe prior to the cauterizing step.

19. A method as claimed in claim 16, wherein the severing step comprises resiliently displacing the roller.

20. A method as claimed in claim 16, further comprising retracting the roller prior to the cutting step.

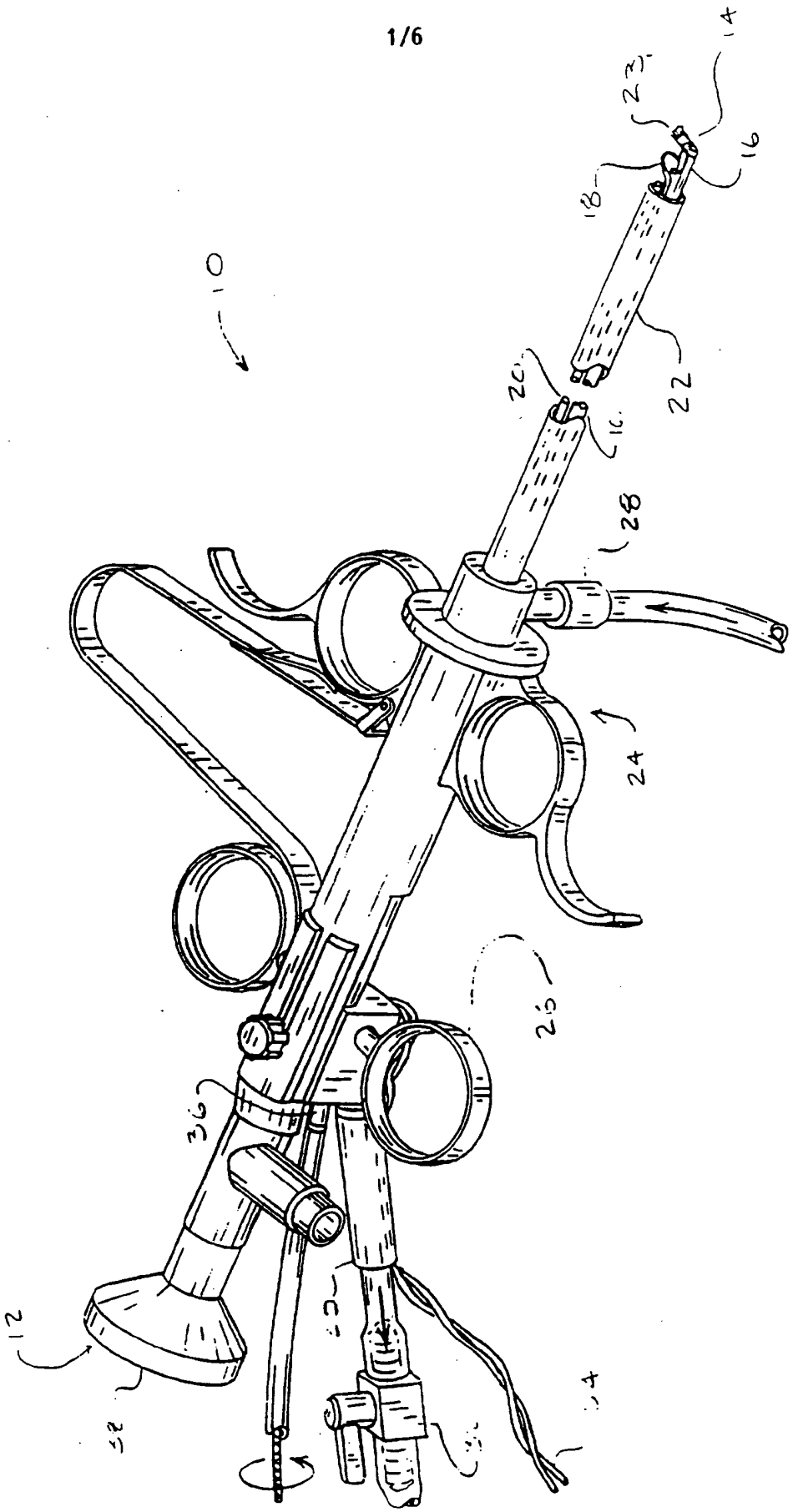


FIG. 1

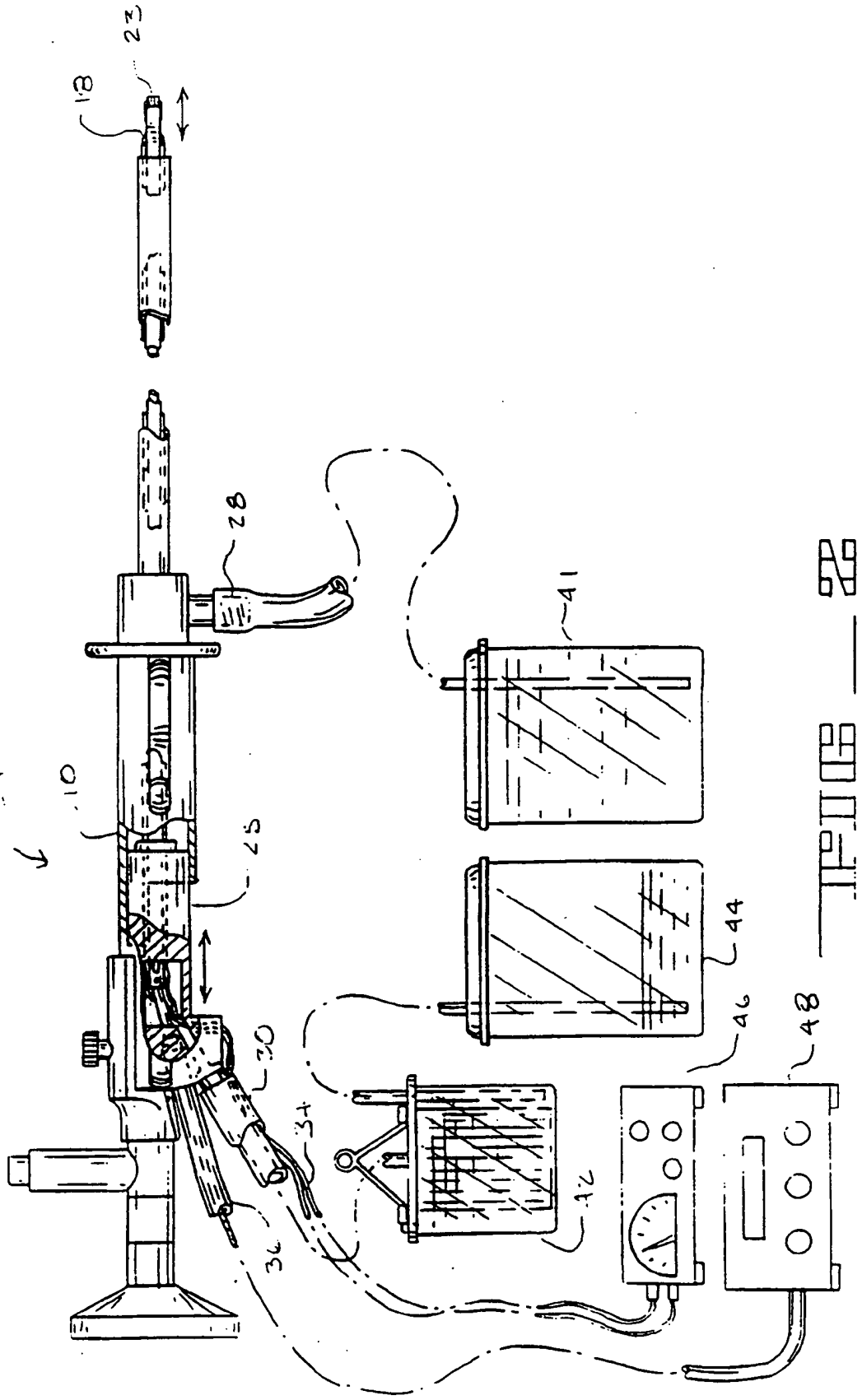


FIG. 2

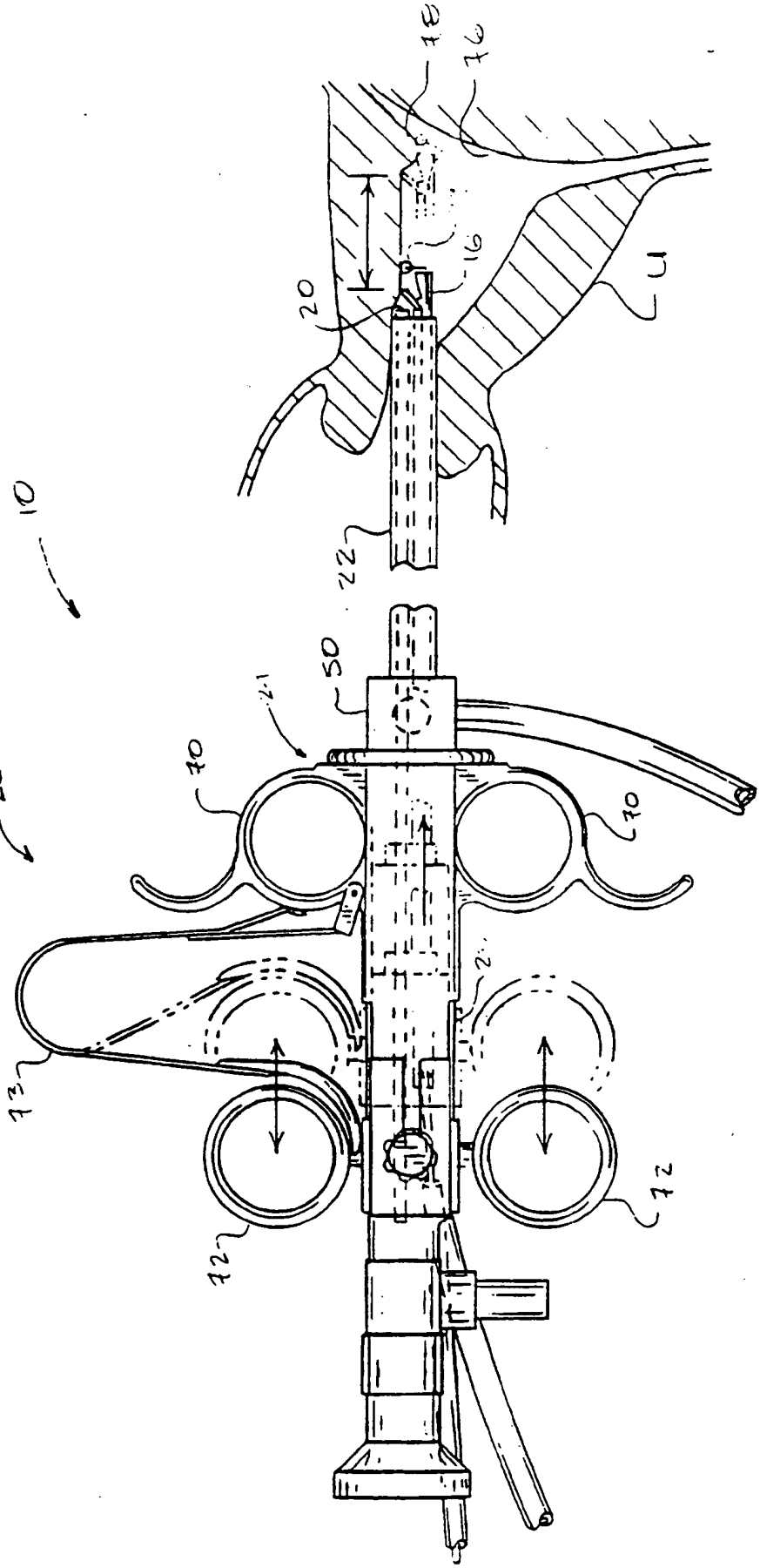


FIG. 3A

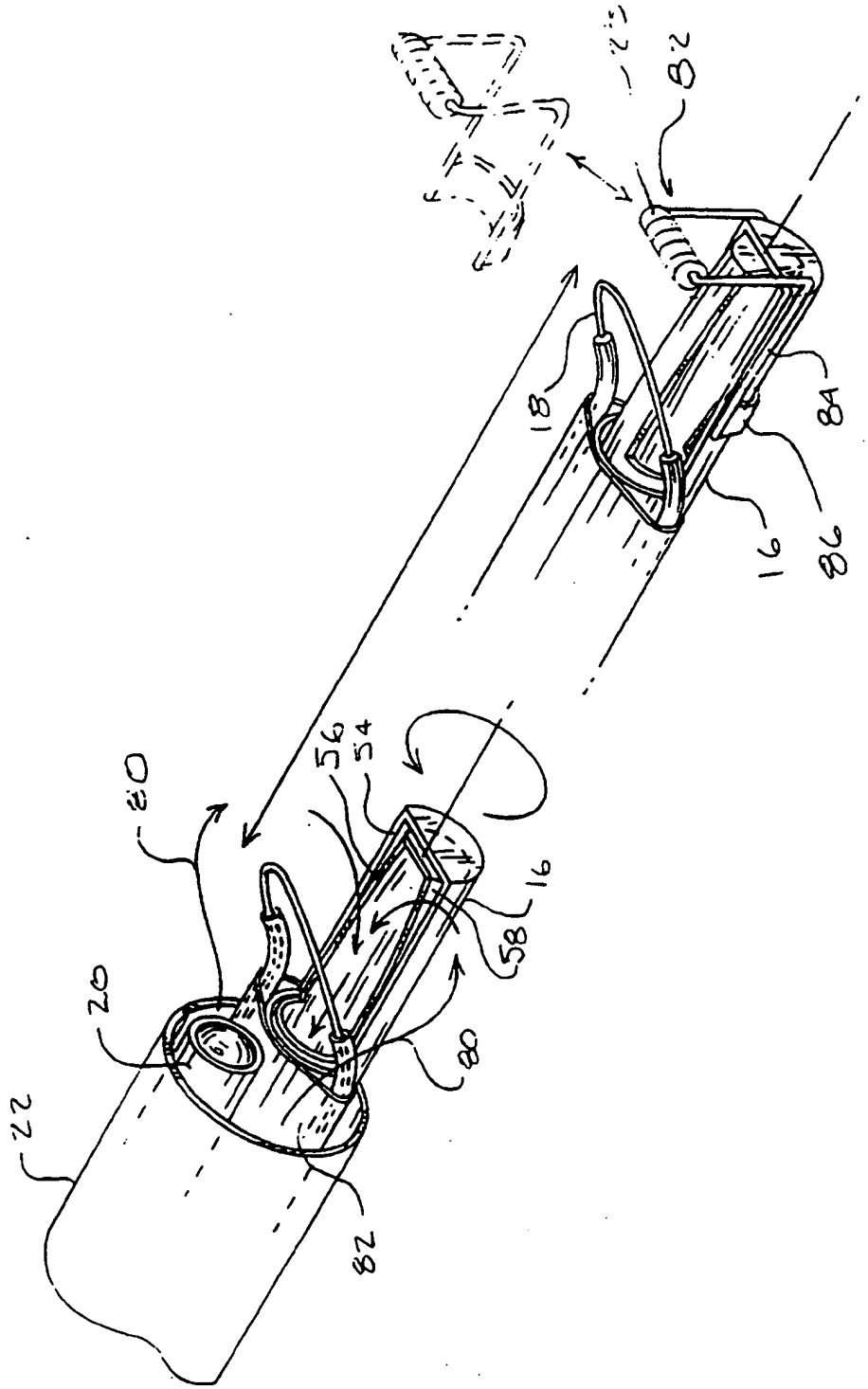


FIG. 4

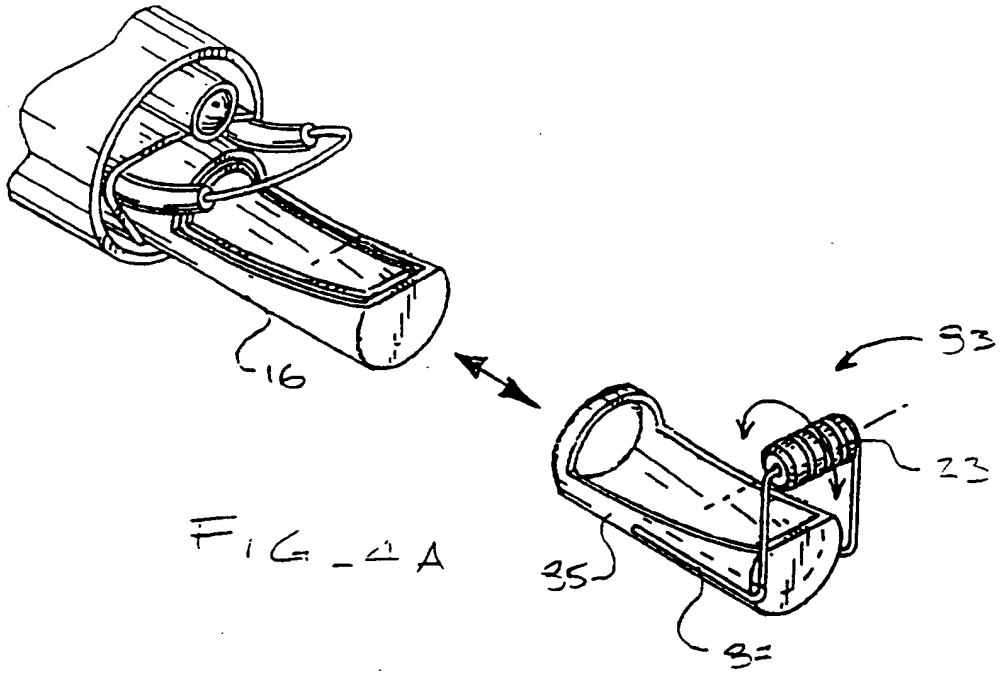


FIG_4A

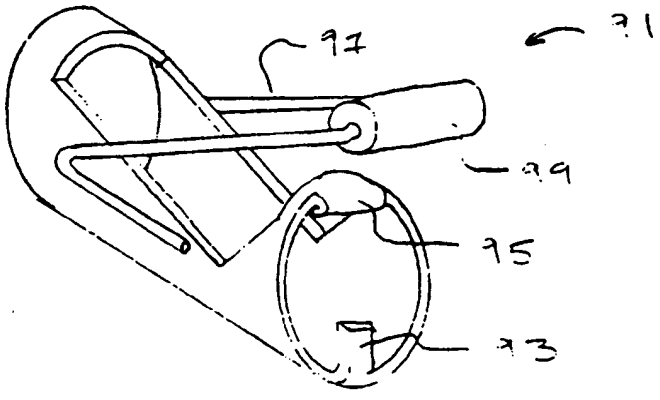


FIG_4B

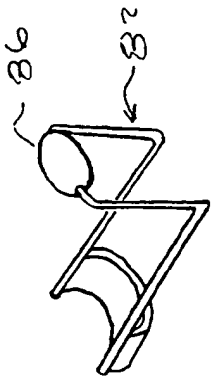


FIG 5

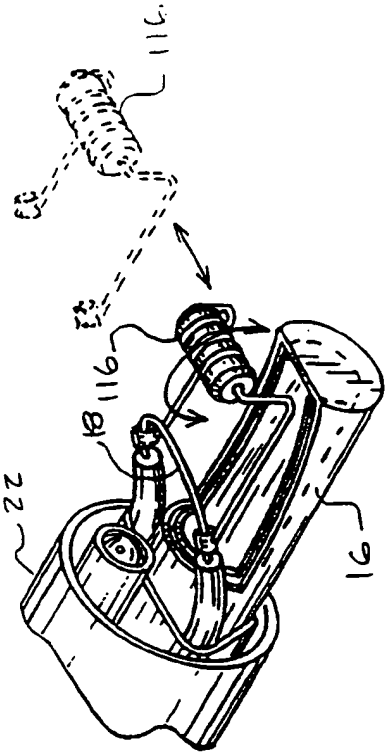


FIG 8

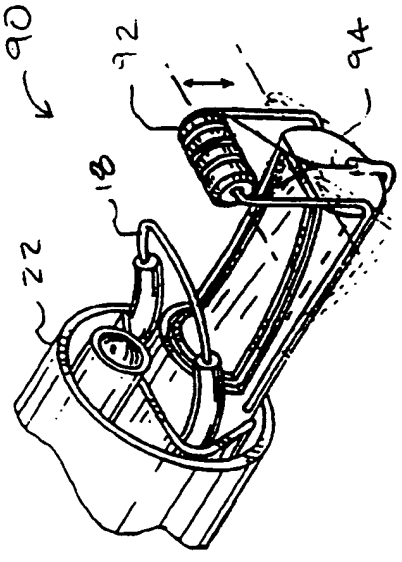


FIG 6

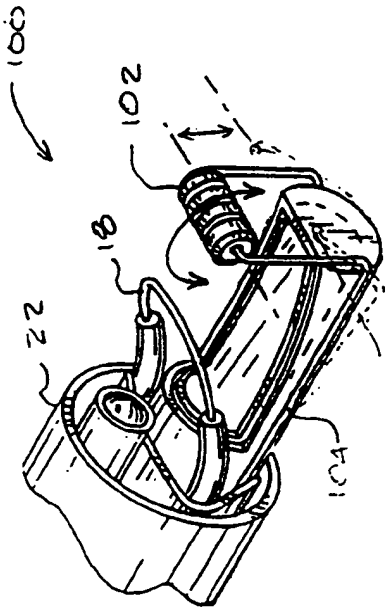


FIG 7

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